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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,832	06/01/2001	Michel Sadclain	830002-2003.1	3724

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EXAMINER

LI, QIAN J

ART UNIT PAPER NUMBER

1632

10

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872,832

Applicant(s)

SADELAIN ET AL.

Examiner

Q. Janice Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-66 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S. C. 121:

- I. Claims 1, 4-17, 34, 39 are drawn to a parental artificial antigen presenting cell (AAPC) expressing b2-microglobulin and at least one exogenous accessory molecule. Classified in class 435, subclass 455
- II. Claims 2, 4-22, 34, 35, 39 are drawn to a parental artificial antigen presenting cell (AAPC) expressing b2-microglobulin, at least one exogenous accessory molecule, and a HLA molecule of a single type. Classified in class 435, subclass 455.
- III. Claims 3-37, 40 are drawn to a parental artificial antigen presenting cell (AAPC) expressing b2-microglobulin, at least one exogenous accessory molecule, a HLA molecule of a single type, and at least one exogenous T cell-specific epitope. Classified in class 435, subclass 455
- IV. Claims 3-35, 38-40 are drawn to a parental artificial antigen presenting cell (AAPC) expressing b2-microglobulin, at least one exogenous accessory molecule, and a HLA molecule of a single type, and further comprising at least one exogenous T cell-specific epitope that is loaded to the AAPC. Classified in class 435, subclass 455
- V. Claims 41 and 42 are drawn to a method of activating cytotoxic T lymphocytes. Classified in class 435, subclass 375.
- VI. Claims 43 and 44 are drawn to a composition comprising CTLs. Classified in class 435, subclass 325.

- VII. Claim 45 is drawn to a method of treating a patient comprising administering to the patient the AAPC of group III or IV. Classified in class 424, subclass 93.21.
 - VIII. Claims 46 and 47 are drawn to a method of treating a patient comprising administering to the patient the CTLs of group VI. Classified in class 424, subclass 93.1.
 - IX. Claim 48 is drawn to a method of screening for accessory molecules using AAPCs of group III or IV. Classified in class 435, subclass 6 and 7.1.
 - X. Claims 49-53 are drawn to a method of screening for T cell-specific antigens using AAPCs of group II. Classified in class 435, subclass 6 and 7.1.
 - XI. Claims 54-66 are drawn to a method of identifying antigen-specific CTLs using AAPCs of group III or IV. Classified in class 435, subclass 6 and 7.1.
2. The inventions are distinct, each from the other because of the following reasons.
- Inventions I-IV and VI are independent or distinct inventions. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, each of the groups I-IV is drawn to a distinct AAPC, i.e. they are structural different in the type of HLA molecule, the presence/absence of a T cell-specific epitope, and how such epitope is associated with the AAPC. Group VI is drawn to a different cell type, i.e. cytotoxic T lymphocyte. The different products are distinct in chemical structure and would have different biological function, as well as modes of operation when used as therapeutic and diagnostic agents, thus require distinct search criteria and technical consideration.

Inventions V, VII-XI are independent or distinct inventions. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are drawn to different methods for activating CTLs, for treating a patient with different type of cells, and different methods for screening of accessory molecules, antigens, and antigen-specific CTLs. Each of the groups differs in the starting materials and agents used in the process, or the method steps and mode of operation. The different methods have distinct technical considerations, and search criteria.

Inventions VI and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the CTL can be made by a materially different process, such as co-culture with a natural occurring APC, or isolated from a subject.

Inventions VII and III or IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of group III or IV could be used in a materially different process such as an *in vitro* screening process; the process of group VII could be practiced with a materially different product, such as a different AAPC or CTL. This analysis also applies to groups VIII and VI; IX and III, IV; or XI and III, IV; or X and II.

The differences of the Inventions I-XI are further underscored by their divergent classification and independent search criteria.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search criteria, it would impose an undue burden to the Office if all the groups are examined together, thus, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

Inventions I-IV are directed to a multitude of specific AAPCs with different utilities, each comprising specific combinations of an exogenous accessory molecule, an HLA of a single type, and a T cell-specific epitope. Depending on the specific combination of elements carried on the AAPC, the utility of the AAPCs may be distinct. Each species of AAPC is defined by 1) a specific accessory molecule; 2) the presence or absence of a HLA molecule of a single type; 3) the presence or absence of a specific T-cell specific epitope. If one of the groups I-IV is elected, further election of a species drawn to a specific combination defining a specific AAPC is necessary.

Each of the inventions V, VII-XI is directed to method using a multitude of specific AAPCs as defined above. If one of the groups V, VII-XI is elected, further election of a species drawn to a AAPC is necessary.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally

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held to be allowable. Currently, all claims are generic, i.e. no single claim identifies a specific AAPC.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

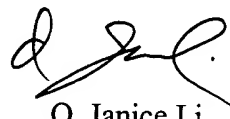
application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).



Q. Janice Li
Examiner
Art Unit 1632

QJL
September 30, 2003